In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 22-832V

* *	Chief Special Master Corcoran
KIMBERLY DEVAUGHN, *	
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Petitioner, *	Filed: February 10, 2025
*	
v. *	
*	
SECRETARY OF HEALTH AND *	
HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

Nathaniel Enos, Conway Homer, P.C., Boston, MA, for Petitioner.

Zoë Wade, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On August 1, 2022, Kimberly DeVaughn filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleges that she suffered a "demyelinating neuropathy" after receipt of the tetanus-diphtheria ("Td") vaccine on August 5, 2020. Petition (ECF No. 1).

I determined that this matter could be fairly resolved via ruling on the record, and both sides filed briefs in support of their positions. Petitioner's Brief, dated July 18, 2024 (ECF No. 31) ("Br."); Respondent's Opposition, dated Sep. 30, 2024 (ECF No. 33) ("Opp."); Petitioner's Reply,

[1] Because this Decision contains a reasoned explanation for my actions in this case, it must be posted on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

dated Oct. 10, 2024 (ECF No. 34) ("Reply"). Now, for the reasons discussed in more detail below, I hereby deny entitlement. Petitioner has not preponderantly established that her chronic inflammatory demyelinating polyneuropathy ("CIDP") – the diagnosis best supported by the record – could be, or was, caused by the Td vaccine.

I. Factual Background

Petitioner was born on August 2, 1966, and was 54 years old at the time of the relevant vaccination. Ex. 2 at 1. Her medical history was significant for anxiety and depression, irritable bowel syndrome, sciatica, arthralgias (joint pain/stiffness), and chronic back pain. Ex. 9 at 26-30.

Vaccination and Initial Neurologic Symptoms

On August 5, 2020, Petitioner received the Td vaccine during a wellness visit with her primary care provider ("PCP"). Ex. 1 at 2. There is no record evidence of any immediate reaction, or concern about the impact of the vaccine on Petitioner's subsequent health.

Two weeks later, on August 20, 2020, Petitioner began to experience numbness and tingling in her toes. Declaration of Kimberly DeVaughn, dated July 29, 2022 (ECF No. 8) ("DeVaughn Dec."). The tingling subsequently progressed over the next day to her foot and her hands. *Id.* at 2. By August 23, 2020, Petitioner reported that she was shuffling rather than walking, and her calves "felt like they had a hard baseball in them." *Id.*

On August 24, 2020, Petitioner returned to her primary care physician ("PCP") complaining of numbness and tingling in both legs (right greater than left) extending to her toes, as well as numbness and tingling in both hands and her fingers. Ex. 9 at 20. Petitioner reported the duration of her symptoms was five days (consistent with her onset statements found in her witness declaration). *Id.* X-rays of her cervical and lumbosacral spine and a physical examination revealed normal findings. *Id.* at 22. Petitioner's assessment included numbness and tingling, low back pain, and cervicalgia (neck pain). *Id.* She was administered a non-steroidal anti-inflammatory injection, prescribed oral medications, and advised to return if her symptoms worsened or persisted. *Id.* at 23. She also began physical therapy ("PT") around this time, attending 30 PT sessions through January 20, 2021. Ex. 6 at 3-29.

On August 31, 2020, Petitioner saw orthopedist Patrick Bold, M.D., reporting a ten-day history of progressive weakness of both her upper and lower extremities, along with significant lower back pain and difficulty walking. Ex. 5 at 9. On physical examination, Petitioner exhibited an unsteady, wide-based gait and station, as well as weakness and absent deep tendon reflexes ("DTRs") in the upper and lower extremities. *Id.* Petitioner also demonstrated abnormal sensation with stocking-glove tingling in the hands and feet. *Id.* Dr. Bold diagnosed Petitioner with progressive difficulty with ambulation (ability to walk) and weakness and numbness of the upper

and lower extremities. *Id.* He advised Petitioner to go directly to the Emergency Department ("ED") for a neurological and possibly neurosurgical evaluation. *Id.*

Petitioner thereafter went to the Parkwest Medical Center ED, where she was admitted for neurological work-up with concern for possible Guillain-Barré syndrome ("GBS"). Ex. 4 at 87. Petitioner reported that her symptoms began with numbness and tingling of her toes that progressed up her legs, and later involved her hands and upper arms. *Id.* At that time, she was unable to get out of a chair without pushing herself up and was unable to walk without assistance. *Id.* The admitting physician, Dr. Jennifer Mosley, diagnosed her with an unspecified form of polyneuropathy, and ordered a lumbar puncture ("LP")[3] and MRI. *Id.* at 88. Dr. Mosley further recommended a nephrology consultation to arrange for plasmapheresis,[4] which was started on September 1, 2020. *Id.* at 81, 88, 91.

Petitioner was hospitalized for six days and discharged with a diagnosis of GBS. Ex. 4 at 76. While admitted, Petitioner underwent a cervical spine MRI which showed multilevel degenerative changes and central and foraminal stenosis (abnormal narrowing of spinal canal), but no cord signal abnormality. *Id.* at 77. Her LP showed elevated protein at 418.2 mg/dL. *Id.* at 78, 108. Venous and arterial ultrasounds of the lower extremities were negative for deep venous thrombosis (blood clot) and hemodynamically significant stenosis, respectively. *Id.* at 79-80. On September 4, 2020, following five days of plasmapheresis, Petitioner reported improvement in her weakness and was able to go to the bathroom with a walker, although her numbness was still present. *Id.* at 97. She was discharged home the following day with a prescription for gabapentin and directions to establish care with a neurologist for her GBS and to follow up with her PCP. *Id.* at 82. Her condition at that time was reportedly "dramatically better." *Id.* at 115.

Post-Hospitalization Treatment

On September 16, 2020, Petitioner visited her PCP for post-hospitalization follow up. Ex. 9 at 7. On exam, she exhibited absent DTRs in the upper and lower extremities, but normal strength. *Id.* at 8. Petitioner was referred to a neurologist, Dr. Thea Cross, for follow-up regarding her diagnosed GBS and to a neurosurgeon, Dr. Joel Ragland, for follow-up regarding her abnormal cervical MRI. *Id.*

On September 28, 2020, Petitioner attended her first appointment with Dr. Cross, who wrote in the relevant record: "54-year-old female with a history of tetanus vaccine in August with

[3] A lumbar puncture involves "the withdrawal of fluid from the subarachnoid space in the lumbar region, usually between the third and fourth lumbar vertebrae, for diagnostic or therapeutic purposes." *Lumbar puncture*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=101105&searchterm=lumbar+puncture (last visited Jan. 13, 2025).

[4] A sick person's plasma can contain antibodies that attack the immune system. Plasmapheresis, also known as a plasma exchange, is a process in which the blood plasma is separated from the blood cells and replaced with clean plasma free of the putative disease-causing antibodies. *Headline for Plasmapheresis*, Northwestern Medicine, https://www.nm.org/conditions-and-care-areas/treatments/plasmapheresis (last visited Jan. 13, 2025).

Guillain-Barre syndrome in September." Ex. 7 at 4. Petitioner reported that she was doing great but was experiencing increasing paresthesia (tingling and numbness) in her right foot and hand over the prior few days. *Id.* Dr. Cross advised Petitioner to give it more time before resuming full activities, continue with gabapentin, and return for a recheck in two weeks. *Id.* at 6.

On October 8, 2020, Petitioner was advised to go to the ED after she contacted Dr. Cross's office with complaints of increased symptoms. Ex. 4 at 886. Petitioner stated that for the previous two weeks, she had experienced increasing numbness in her hands and feet, which spread up to her ankles, and caused difficulty ambulating. *Id.* Petitioner further stated that she had returned to using her walker. *Id.* Petitioner was admitted to the hospital a second time, for additional evaluation. *Id.* There, she was seen by Dr. Sergio Loaiza, M.D., for a neurological consultation. *Id.* at 895. Dr. Loaiza diagnosed a treatment-related fluctuation in Petitioner's GBS following plasma exchange and recommended two days of IVIG[5] as well as physical and occupational therapy assessments. *Id.* at 896-97. Petitioner received IVIG for two days and was discharged home with plans to follow up with Dr. Cross about possibly undergoing an EMG[6] or nerve conduction study. *Id.* at 886.

On October 21, 2020, Petitioner followed up with Dr. Cross, who wrote, "54-year-old female with a history of inflammatory neuropathy after tetanus booster vaccinations." Ex. 7 at 17. Petitioner reported that she felt better since her hospitalization and that her strength was dramatically improved with IVIG, but she still struggled to balance with her eyes closed. *Id.* On exam, Petitioner exhibited absent DTRs, positive Romberg (balance test) results, wide-based gait, mild tremulousness, and mildly unsteady heel-to-shin test results. *Id.* Due to the resurgence of symptoms, Dr. Cross was concerned that Petitioner may have an "atypical case" and recommended an EMG and a Mayo Clinic motor neuropathy lab panel to look for anti-ganglioside antibodies,[7] monoclonal gammopathy, or other etiology. *Id.* at 19. Dr. Cross noted the purpose of additional testing was to see if Petitioner should receive additional IVIG every four-to-six weeks. *Id.* On November 9, 2020, Petitioner underwent an EMG/NCS performed by Dr. Cross. Ex. 7 at 45. The results were consistent with a moderate demyelination polyradiculopathy. *Id.*

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[5] "Intravenous Immunoglobulin (IVIG)" is defined as "[a] therap[y] prepared from a pool of immunoglobulins (antibodies) from the plasma of thousands of healthy donors. Immunoglobulins are made by the immune system of healthy people for the purpose of fighting infections…IVIG/SCIG work in different ways to prevent the body from attacking itself and to decrease several types of inflammation in the body." IVIG, https://rheumatology.org/patients/intravenous-immunoglobulin-ivig (last visited Dec. 30, 2024).

[6] "Electromyography (EMG) measures muscle response or electrical activity in response to a nerve's stimulation of the muscle. The test is used to help detect neuromuscular abnormalities." *Electromyography (EMG)*, John Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/electromyography-emg (last visited Jan. 14, 2025).

[7] Anti-ganglioside antibodies are associated with several immune-mediated peripheral neuropathies, including GBS. *Ganglioside Antibodies*, NHS, Oxford University Hospitals, https://www.ouh.nhs.uk/immunology/diagnostic-tests/tests-catalogue/ganglioside-antibodies.aspx (last visited Jan. 14, 2025).

On November 25, 2020, Petitioner returned to see Dr. Cross, and advised she felt like she had finally turned the corner and her strength was back to normal, with fewer paresthesia as well, although her balance was still a "little off." Ex. 7 at 29. Dr. Cross noted Petitioner's lab testing results were negative for ganglioside antibodies, and recommended she remain off work until January, but advised Petitioner that she could resume driving. *Id.*

Treater Acceptance of CIPD Diagnosis in 2023

Petitioner continued to experience some neurologic symptoms in early 2021. *See, e.g.*, Ex. 3 at 6 (January 13, 2021 visit with new treater). But she nevertheless had improved enough to express a desire to limit medications due to their side effects *Id.* Indeed, other than treatment of unrelated concerns, Petitioner thereafter did not require additional medical assistance for the rest of 2021 (and 2022 as well) relating to her prior neuropathic symptoms.

In August 2023, however, Petitioner returned to Dr. Cross, now reporting a renewal of tingling and discomfort in her lower extremities and some tremulousness. Ex. 33 at 21. Petitioner advised that her symptoms were annoying but not severe enough that she wanted to add any medications. *Id.* A physical examination revealed mildly decreased sensation at the sock line, absent DTRs, and mild postural tremor in her upper extremities bilaterally, but normal strength and stable gait. *Id.* Dr. Cross ordered lab tests to evaluate potential etiologies for Petitioner's tremor and recommended a repeat EMG/NCS. *Id.* at 22. A September 18, 2023, EMG/NCS showed findings consistent with demyelinating polyradiculoneuropathy. Ex. 36 at 3-4.

On October 18, 2023, Petitioner completed a repeat LP, which now showed elevated protein and red blood cells. Ex. 35 at 124-125. On October 24, 2023, Petitioner followed up with Dr. Cross and reported increased soreness and muscle fatigue, as well as increased difficulty with balance. Ex. 33 at 14. Dr. Cross noted trace weakness in her lower extremities with absent reflexes, but normal sensation. *Id.* Dr. Cross now diagnosed Petitioner with CIDP and recommended further laboratory tests and IVIG. *Id.* Petitioner completed five days of IVIG from December 4 through December 8, 2023. Ex. 34 at 15-24.

On January 22, 2024, Petitioner saw Dr. Cross at a follow-up appointment and was noted to be responding well to IVIG. Ex. 33 at 7. Petitioner complained of discomfort in her shoulders and upper arms, as well as numbness in her feet. *Id.* A physical examination revealed mildly reduced strength in the lower extremities but normal strength in the upper extremities, absent DTRs, but no tremor and normal heel-to-shin test results. *Id.* Dr. Cross recommended that Petitioner continue with IVIG every four weeks. *Id.* Petitioner continued with regular IVIG treatments through March of 2024. *See generally* Ex. 34. No further medical records regarding the relevant injury have been filed.

II. Expert Reports

A. Petitioner's Expert – Sami Khella, M.D.

Dr. Khella, a neurologist, prepared two written reports in support of the claim. Report, dated August 23, 2023, filed as Ex. 20 (ECF No. 20-1) ("First Khella Rep."); Report, dated July 15, 2024, filed as Ex. 37 (ECF No. 29-1) ("Second Khella Rep.").

Dr. Khella is the Chief of the Department of Neurology, Director of Clinical Electrophysiology, and the Director of Clinic Neurophysiology at Penn Presbyterian Medical Center. First Khella Rep. at 1; CV, dated November 2022, filed as Ex. 21 (ECF No. 20-2) ("Khella CV"). He has been a Professor of Clinical Neurology at the University of Pennsylvania School of Medicine since 2014. Khella CV at 1. He received his medical degree from University of Pennsylvania, where he also completed his residency in medicine and neurology. *Id.* He is board certified in Electrodiagnostic Medicine, and Psychiatry and Neurology, with an added qualification in Clinical Neurophysiology. *Id.* at 2. Dr. Khella devotes a substantial portion of his time to diagnosing and treating patients with a variety of neurologic diseases. First Khella Rep. at 2. He has held editorial positions for several medical journals and has given many lectures by invitation on various topics concerning neurology and electrophysiology. *Id.* at 1. He has also published over thirty peer-reviewed medical articles. *Id.*

First Report

Dr. Khella's initial expert report (prepared at almost the same time Petitioner had experienced a flare-up of neurologic symptoms – but prior to her receipt of a CIDP diagnosis) set forth the opinion that a causal relationship between Petitioner's Td vaccination and her GBS was more than likely. First Khella Rep. at 5. Dr. Khella noted that Petitioner's symptoms, examination, clinical course, and CSF/EMG findings were all consistent with a diagnosis of GBS. *Id.* at 3. Thus, EMG testing showed evidence of demyelination and cytoalbuminologic dissociation in the cerebrospinal fluid obtained from her LP – meaning Petitioner possessed elevated proteins without an increase in the number of white blood cells. *Id.* She also had "the typical time course of acute onset of a paralyzing neuropathy that then stabilized within a few weeks." *Id.*

GBS, Dr. Khella explained, is mediated by an autoimmune process. First Khella Rep. at 4. It is understood to result from an "incorrect" immune attack against certain elements of peripheral nerves, namely myelin. *Id.* This leads to numbness, tingling, and muscle paralysis. *Id.* Unlike other autoimmune disorders, GBS operates like a post-infectious disease, in that it is often triggered by prior/resolved illness (or immunization). *Id.* While the exact mechanisms of the immune attack remain unclear, they are thought to include activation of macrophages, complement systems, and T-cell mediated cytotoxicity, release of many cytokines, and activation of B lymphocytes. *Id.* Molecular mimicry is an important concept in the development of GBS (in which sequential similarities between amino acid sequences in protein components, or molecular structures, and those of a self-tissue result in the production of antibodies that mistakenly attack self (here, nerve myelin)). *Id.*

Dr. Khella also discussed the role that T-cells play in the development of GBS in the context of exposure to the wild tetanus toxin (which could be *somewhat* analogous to the reaction the vaccine elicits). First Khella Rep. at 4. He cited a 2017 case report involving two patients who developed GBS following a tetanus infection. *See* S.J. Im et al., *Guillain-Barré Syndrome after Generalized Tetanus Infection*, 19 Annals of Clinical Neurophysiology 64-67 (2017), filed as Ex. 25 (ECF No. 20-6) ("Im"). In an attempt to explain the causal link between the patients' tetanus infections and their subsequent development of GBS, Im's authors noted that ganglioside-specific T-cell reactivity is an important cause of nerve damage. *Id.* at 67. The authors then proposed that the terminal carboxylase group in the heavy chain of tetanus toxin (tetanospasmin) is a strong inducer of T-cell activity, inducing an attack on gangliosides, and in turn resulting in damage to the patients' nerves. *Id.*

To connect GBS with vaccination, Dr. Khella pointed to several case reports of GBS developing within a few weeks of the administration of tetanus-containing vaccines. *See*, *e.g.*, K. Kongbunkiat et al., *Clinical Manifestations and Outcomes of Guillain-Barré Syndrome after Diphtheria and Tetanus Vaccine (dT) during a Diphtheria Outbreak in Thailand: A Case Series*, 19 Neurology Asia 149, 154 (2014), filed as Ex. 23 (ECF No. 20-4) ("Kongbunkiat") (reporting four cases of GBS after administration of the dT vaccine during a diphtheria outbreak in Thailand, and suggesting that the vaccine may stimulate the immune system and cause autoantibodies against peripheral nerves); R. Bakshi & M. Graves, *Guillain-Barré Syndrome after Combined Tetanus-Diphtheria Toxoid Vaccination*, 147 J. of Neurological Sci. 201, 202 (1997), filed as Ex. 24 (ECF No. 20-5) ("Bakshi") (offering no causal explanation for a patient who developed GBS four days after receipt of the dT vaccination); H. Ammar, *Guillain-Barre Syndrome after Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine: A Case Report*, 5 J. of Med. Case Rep. 502, 503 (2011) ("Ammar") (offering no causal explanation for a patient who developed GBS a few days after receipt of the Tdap vaccination, and noting "the number of cases of GBS observed after a tetanus toxoid-containing vaccine to be less than the number caused by chance alone"), filed as Ex. 27 (ECF No. 20-8); N. Newton Jr. & A. Janati, *Guillain-Barré Syndrome after Vaccination with Purified Tetanus Toxoid*, 80 South Med. J. 1053, 1054 (1987), filed as Ex. 29 (ECF No. 20-10) ("Newton") (patient developed GBS nine days after receipt of a pure tetanus toxoid vaccine; individual thought to have experienced a hypersensitive lymphoblastic transformation to purified tetanus antigen).

In fact, Dr. Khella maintained, the Institute of Medicine (IOM) has deemed plausible the risk of GBS following receipt of a tetanus-containing vaccine. *See Feature Article – Guillain-Barre Syndrome (GBS) & Vaccines: The Risks and Recommendations*, Children's Hospital of Philadelphia: Parents PACK (Sep. 13, 2021), https://www.chop.edu/parents-pack/parents-pack-newsletter/newsletter-archive/feature-article-gbs-vaccines-risks-and-recommendations, filed as Ex. 22 (ECF No. 20-3) ("GBS & Vaccines"). And the 1996 Advisory Committee on Immunization Practices acknowledged that tetanus toxoid can trigger GBS. *See Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions: Recommendations of the Advisory*

Committee on Immunization Practices (ACIP), 45 Morbidity & Mortality Weekly Report (Sep. 6, 1996), https://www.cdc.gov/mmwr/preview/mmwrhtml/00046738.htm, filed as Ex. 31 (ECF No. 20-12). Finally, the Children's Hospital of Philadelphia cautions patients who have developed GBS within six weeks of receiving a tetanus vaccine from receiving a second tetanus-containing vaccine. *See* GBS & Vaccines; A.T. Kroger et al., *General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)*, CDC (2023), https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf., Ex 32 (ECF No. 20-13).

With respect to the onset of Petitioner's illness when measured from vaccination, Dr. Khella again referenced case reports standing for the proposition that GBS can develop within six weeks of receiving a tetanus vaccine. *See* Kongbunkiat; Bakshi. Thus, Petitioner's two-week onset fell well within a medically acceptable timeframe. First Khella Rep. at 4.

Second Report

Dr. Khella's second report mainly discussed Petitioner's revised CIDP diagnosis, and how the Td vaccine could have been causal of this illness as much as of GBS. He accepted the diagnostic revision, noting that it had only happened after Petitioner's symptoms recurred (since GBS is considered an acute and monophasic illness). Second Khella Rep. at 1. Additionally, Petitioner had persistent CSF protein elevation in October 2023 and continued evidence of demyelination on EMG. *Id.* Dr. Khella deemed such a diagnostic revision to be commonplace, since CIDP and GBS present with similar symptoms in the early stages, with CIDP only evident when a Petitioner's course reveals a waxing of symptoms thought previously to have been controlled.

Dr. Khella readily borrowed reasoning applicable to how a tetanus-containing vaccine could cause GBS, even though the ultimate diagnosis was now different – perhaps in large part because he did not find the distinction meaningful for purposes of causation. CIDP, like GBS, is a demyelinating neuropathy with an immune-mediated basis. Second Khella Rep. at 1. Even if molecular mimicry cannot explain *all* autoimmune diseases, it remains a viable mechanistic explanation for many demyelinating neuropathies, including CIDP. *Id.* And he offered some additional literature showing the purported impact of exposure to the tetanus *toxin* – although such items were not specific to CIDP, and the Td vaccine contains only tetanus *toxoid*. *See* M. Shahani et al., *Neuropathy in Tetanus*, 43 J. of Neurological Sci. 173-82 (1979), filed as Ex. 42 (ECF No. 29-6) ("Shahani"); J.H. Lee et al., *Generalized Tetanus Could be Complicated with Guillain-Barré syndrome*, 48 Int'l J. of Infectious Diseases 20-21 (2016), filed as ECF No. 39 (ECF No. 29-3). The authors of Shahani concluded that that the link between tetanus and neurologic damage is due to "an action of tetanus toxin affecting the distal parts of both sensory and motor nerves." *Id.* at 181. A vaccine containing tetanus-based elements might have the same effect, Dr. Khella reasoned.

Dr. Khella did also attempt to offer literature more specific to CIDP, but it was not facially robust. For example, he referenced a nearly 50 year-old case report describing a patient who

purportedly experienced CIDP in reaction to exposure to the kind of tetanus vaccine component at issue here. J.D. Pollard & G. Selby, *Relapsing Neuropathy Due to Tetanus Toxoid*, 37 J. Neurol. Sci. 113-25 (1978), filed as Ex. 30 (ECF No. 20-11) ("Pollard & Selby"). The patient's demyelinating neuropathy, which was never officially diagnosed as CIDP, re-occurred three times, each following a tetanus vaccination. Pollard & Selby at 113. While the reoccurrence established evidence of a possible causal connection in *this individual patient*, no potential causal mechanism was presented or discussed.

Another study, Dr. Khella maintained, demonstrated that patients with CIDP who received a tetanus-containing immunization often suffered a relapse. J. Pritchard et al., *Risk of Relapse of Guillain-Barré Syndrome or Chronic Demyelinating Inflammatory Polyradiculoneuropathy Following Immunization*, 73 J. Neurology Neurosurgery Psychiatry 348, 348–49 (2002), filed as Ex. 40 (ECF No. 29-4) ("Pritchard"). In Pritchard, the GBS Support Group (a British patient organization) posted 3,000 questionnaires to its members, asking them to describe any symptoms they had experienced within six weeks of vaccination that might be suggestive of recurring GBS or worsening CIDP. Pritchard at 348. Of the 23 patients who received a tetanus vaccine after CIDP onset, two reported relapses of their CIDP symptoms post-vaccination. *Id.* But Pritchard's authors themselves acknowledged the study's limitations, noting that "it is intuitively likely that more patients who experienced symptoms following immunization responded to the questionnaire." *Id.* at 349. Consequently, the authors conceded that "the true risk of relapse following immunizations after GBS or CIDP may be less than those discovered in this audit." *Id.*

Finally, Dr. Khella noted an alternative explanation for Petitioner's CIDP: the vaccine's diphtheria component. A diphtheria natural infection, he maintained, can lead to neuropathy in 75% of severe infections. *See Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality* (K. Stratton et al., eds., 2012), filed as Ex. 44 (ECF No. 29-8).[8] He also referenced an article that purported to identify a homology between diphtheria and myelin-associated protein. *See* S.L. Bavaro et al., *Pentapeptide Sharing between Corynebacterium Diphtheria Toxin and the Human Neural Protein Network*, 33 Immunopharmacology Immunotoxicology 360-72 (2011), filed as Ex. 38 (ECF No. 29-2) ("Bavaro"). The authors of Bavaro discovered that 80 diphtheria toxin pentapeptides are disseminated through 94 human proteins that are crucially involved in the pathways that regulate and modulate the activities of the peripheral and central nervous system. *Id.* at 164. This high level of peptide sharing suggested a cross-reactivity risk that could burden active vaccination procedures with autoimmune reactions. *Id.* at 168.

[8] I have been unable to find support for this contention in the referenced literature cite.

B. Respondent's Expert – You-Wen He, M.S., Ph.D.

Dr. He, a medical doctor and academic immunologist, prepared one report for Respondent. *See* Report, dated November 2, 2023, filed as Ex. A (ECF No. 22-1) ("He Rep.").[9]

Dr. He is a Professor of Integrative Immunobiology in the Department of Integrative Immunobiology at Duke University School of Medicine. He CV, dated November 14, 2023, filed as Ex. B (ECF No. 22-12) ("He CV"). He received his medical degree from the Fourth Military Medical University in China and received his Ph.D. from the Miami School of Medicine. He CV at 1. Dr. He went on to complete a senior fellowship in the Department of Immunology at the University of Washington and completed his residency at Qindu Hospital in China. *Id.* Dr. He has been conducting research in immunology since he graduated from medical school in 1986. He Rep. at 1. Over the past 27 years, he has been invited to lecture nationally and internationally on the topic of host immune responses to microbial infections and tumors. *Id.* Dr. He has also served as a co-Principal Investigator for four clinical trials focusing on cancer immunotherapy using personalized cancer vaccines. *Id.* Dr. He has been published extensively and has served as an ad hoc reviewer for more than 30 scientific journals. *Id.*; He CV at 7-18.

Dr. He maintained that no reliable evidence supported a causal link between the Td vaccine and GBS. He Rep. at 10. Although the pathologic mechanisms that facilitate the development of GBS have not been conclusively established, cross-reactive antibodies may play a role in its immunopathogenesis, attacking self-structures due to molecular mimicry similarities with foreign antigens. *Id.* at 4; B. van den Berg et al., *Guillain-Barre Syndrome: Pathogenesis, Diagnosis, Treatment and Prognosis*, 10 Nature Rev. Neurology 469-82 (2014), filed as Ex. A.1 (ECF No. 22-2) ("van den Berg"). But Dr. He deemed it difficult to evaluate the explanatory validity of the theory presented in this case, since Dr. Khella had provided no details on the purportedly shared sequences or structures between myelin and any Td vaccine component – simply assuming instead they were *likely* present. He Rep. at 5.

Dr. He also questioned whether molecular mimicry still warranted the same degree of respect as a mechanistic theory with utility in explaining autoimmune diseases, because it "has been strongly challenged by recent scientific evidence." He Rep. at 5. In support, Dr. He referenced a study that compared peptide similarity between viral and human proteomes. D. Kanduc et al., *Massive Peptide Sharing between Viral and Human Proteomes*, 29 Peptides 1755-66 (2008), filed as Ex. A.6 (ECF No. 22-7) ("Kanduc"). Kanduc found that 90% of the viral 5-mer peptides (stretch of 5 amino acids) are repeatedly scattered throughout the human proteome. Kanduc at 1757. If molecular mimicry were per se so predictive of autoimmunity, then these sequence similarities would support a 100% rate of autoimmune disease development following vaccination or infection

[9] Dr. He's sole report was filed shortly after Petitioner's CIDP diagnosis revision, but only discusses GBS as the alleged injury. However, since Petitioner relies substantially on medical and scientific evidence specific more to GBS than CIDP, Dr. He's opinion remains relevant.

– something that obviously does not occur. He Rep. at 6. Thus, mere sequence similarity does not mean molecular mimicry "explains" autoimmune disease in every case. *Id.*; *see also Adverse Effects of Vaccines: Evidence and Causality* (K. Stratton et al., eds., 2012), filed as Ex. A.3 (ECF No. 22-4) ("2012 IOM Rep.") at 70 ("Linear amino acid sequence homology or even similar conformational structure between an exogenous agent and a self-antigen alone are not sufficient to prove that molecular mimicry is the pathogenic mechanism for a disease").

In addition, Dr. He contended that even if molecular mimicry remains a reliable mechanistic theory in explaining some autoimmune conditions (including some forms of GBS), this did not also mean that tetanus-containing vaccines are capable of stimulating production of such autoantibodies due to molecular similarity. Rather (and as the IOM determined), "the mechanistic evidence regarding an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and GBS [is] *lacking*." 2012 IOM Rep. at 558 (emphasis added). This absence of a causal relationship was confirmed in a more recent study. *See* M. Dudley et al., *The State of Vaccine Safety Science: Systemic Reviews of the Evidence*, 20 Lancet Infec. Dis. e80 (2020), filed as Ex. A.4 (ECF No. 22-5) ("Dudley"). Dudley's authors looked at a broad array of literature addressing possible adverse events speculated to be vaccination-associated and found no causal relationship between receipt of the Tdap vaccine and the development of GBS. Dudley at e83-84.

Dr. Khella, by contrast, relied heavily on case reports to connect the Td vaccine to GBS. But, Dr. He argued, such evidence could only establish the existence of a *temporal* relationship between GBS and tetanus-containing vaccines, and did not stand as strong proof of a causal association. He Rep. at 7. And evidence proposing a connection between a wild tetanus infection and GBS, like Im, was also unhelpful, since infection and vaccination are fundamentally different. *Id.* at 8. In particular, the depth of immune responses induced by the tetanus bacterium versus a vaccine containing tetanus *toxoid*[10] is very different, with the body mounting a more comprehensive response to a wild infection that would inherently be more damaging (and correspondingly likely to result in secondary illnesses due to an autoimmune response). *Id.* at 9.

III. Procedural History

This claim was initiated in August 2022. In March 2023, Respondent filed his Rule 4(c) Report contesting entitlement. (ECF No. 16). Petitioner filed an expert report from Dr. Khella in August 2023, and in late October 2023, Petitioner's diagnosis was changed from GBS to CIDP. One week later, in early November 2023, Respondent filed a responsive expert report from Dr. He. In July 2024, Petitioner submitted a supplemental expert report addressing the revised CIDP

[10] A toxoid is "a modified or inactivated bacterial exotoxin that has lost toxicity but retains the properties of combining with, or stimulating the formation of, antitoxin." Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=50428&searchterm=toxoid (last visited Feb. 4, 2025).

diagnosis, along with a Motion for Ruling on the Record. Respondent filed his Opposition and Petitioner followed up with her Reply. The matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner contends that her peripheral neuropathy was caused by receipt of the Td vaccine in August 2020. Reply at 1. In her briefing, Petitioner addresses all three prongs of the test set by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) for causation claims.

Petitioner begins by arguing that she has demonstrated a medical theory that causally connects CIDP to the Td vaccine. Br. at 34. Demyelinating neuropathies like GBS and CIDP are immune-mediated disorders that are caused by a loss of tolerance to self-antigens. *Id.* at 34-36. Petitioner theorizes that this loss of self-tolerance can be caused by vaccines. *Id.* at 36; Kongunkiat at 154 ("Vaccination is believed to stimulate the immune system and cause autoantibodies against peripheral nerves"). To support the contention that tetanus-containing vaccinations can trigger demyelinating peripheral neuropathy, Petitioner lists the case studies cited by Dr. Khella in his first expert report. Br. at 36 (citing Pollard & Selby, Kongbunkiat, Bakshi, Newton). While most of these case studies involve GBS, the authors of Pritchard found a significant risk of recurring CIDP symptoms following a tetanus vaccination. Pritchard at 348-49.

The observed causal link between the Td vaccine and CIDP in such evidence can be explained by molecular mimicry, a theory that is supported by reliable scientific findings. Br. at 37-38. In response to Dr. He's contention that Petitioner did not offer details on the shared antigens between the Td vaccine and myelin, Petitioner referenced Bavaro, which identified homology between diphtheria and myelin-associated proteins. *Id.* at 38. And although Dr. He had argued that homologic similarity was too common in nature to be a suspect factor explaining every autoimmune condition, Petitioner noted that Kanduc (the primary item of literature referenced by Respondent for this point) analyzed *viral* proteomes. Reply at 3. Tetanus and diphtheria, by contrast, are *bacterial* infections, thus diminishing the value of scientific findings relating to the impact of amino acid sequential homology between the components of *proteins* (which is what viruses are). *Id.* at 4.

Petitioner also disputed Dr. He's argument that the IOM's purported allowance of a possible tetanus-GBS connection was dated or erroneous. Br. at 39. In reaction, Petitioner cited *Harris v. Sec'y of Health & Hum. Servs.*, No. 18-944V, 2023 WL 2583393, at *24 (Fed. Cl. Spec. Mstr. Feb. 21, 2023), which found that both the 1994 IOM report, which favors a causal relationship between tetanus-containing vaccines and GBS, and the 2012 report, which found insufficient evidence supporting a link between the Tdap vaccine and GBS, had probative value –

but that the subsequent 2012 report should not be accepted at the exclusion of the 1994 report. *Harris*, 2023 WL 2583393, at *24.

Regarding the second, "did cause" *Althen* prong, Petitioner highlights the opinions of her treating physicians. Br. at 42-44. Treaters like Dr. Cross appeared to link the vaccination to Petitioner's injury in their appointment notes (albeit when the diagnosis was still GBS). *Id.* at 44; *See* Ex. 7 at 17 ("54-year-old female with a history of inflammatory neuropathy after tetanus booster vaccinations`"); Ex. 3 at 6 ("She was diagnosed with Guillain barre syndrome in August after she had a tetanus shot with her primary care"). In September 2020, Petitioner's PCP also mentioned the Td vaccine in connection with Petitioner's GBS, writing, "…Neurology mentioned a Tdap done in early August." Br. at 44 (citing Ex. 9 at 7). And no alternative causes for Petitioner's sudden development of demyelinating neuropathy were mentioned or considered by her physicians. Br. at 45.

Finally, Petitioner argues that the onset of her CIDP symptoms fell within a medically acceptable timeframe following vaccination. Br. at 45. Two weeks post-vaccination, Petitioner began to experience numbness and tingling. *Id.* at 46. Dr. Khella's first expert report deemed such an onset to fall "well within the medically acceptable timeframe for an aberrant immune-mediated response following vaccination." First Khella Rep. at 4. In fact, Dr. He even agreed, writing, "a temporal relationship between Ms. DeVaughn's receipt of the Td vaccine and her GBS onset did exist." Br. at 47; He Rep. at 10.

Respondent

Respondent contends that Petitioner has provided insufficient evidence to satisfy her burden under *Althen*. Opp. at 1. Before addressing the three *Althen* prongs, Respondent highlighted the fact that GBS and CIDP are not identical, and should not be treated as such. *Id.* at 14; *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, 2022 WL 4869354, at *22 (Fed. Cl. Aug. 31, 2022) ("Petitioners cannot just 'borrow' what is known about GBS and vaccination generally as a template for proving causation in the context of a CIDP injury."), *mot. for review den'd*, 2023 WL 4117370 (Fed. Cl. 2023), *aff'd,* No. 2023-1816, 2024 WL 2873301 (Fed. Cir. 2024); *see also Nieves v. Sec'y of Health & Hum. Servs.*, No. 18-1602V, 2023 WL 3580148, at *36 (Fed. Cl. May 22, 2023) ("[T]he overlap between GBS and CIDP cannot be employed as a shortcut to entitlement"), *mot. for review den'd*, 167 Fed. Cl. 422 (2023). Respondent also notes that Petitioner cannot circumvent the CIDP diagnosis by generally referring to her injury as a "demyelinating neuropathy." Opp. at 14-15. The evidence supporting a CIDP diagnosis is incontrovertible, making it the relevant injury in this case. *Id.* at 15.

Respondent acknowledges that Petitioner was able to present some evidence of homology between diphtheria toxin and myelin-associated proteins, as in Bavaro. Opp. at 15. But Respondent

argues that this is not necessarily significant, since Petitioner did not offer evidence to suggest any of the identified homologous amino acid sequences *are likely cross-reactive*, let alone capable of instigating CIDP. *Id.* And numerous decisions from the Vaccine Program have recognized the limited utility of amino acid sequence to causation determinations. *Id.* at 16 (citing *Bravo v. Sec'y of Health & Hum. Servs.*, No. 17-501V, 2023 WL 4147146, at *17 (Fed. Cl. Spec. Mstr. May 31, 2023); *K.A. v. Sec'y of Health & Hum. Servs.*, No. 16-989V, 2022 WL 20213037, at *29 (Fed. Cl. Spec. Mstr. Apr. 18, 2022), *mot. for review den'd*, 164 Fed. Cl. 98 (2022), *aff'd*, No. 2023-1315, 2024 WL 2012526 (Fed. Cir. 2024); *A.T. v. Sec'y of Health & Hum. Servs.*, No. 16-393V, 2021 WL 6495241, at *11 (Fed. Cl. Spec. Mstr. Dec. 17, 2021)). In addition, the literature relied upon by Petitioner established that high levels of homology exist between diphtheria and human proteins. Opp. at 17; Bavaro at 360-61 (identifying 4966 shared sequences between diphtheria pentapeptides and human proteins). Such new-found awareness of the vast extent of peptide sharing between microbial and human proteins, Respondent contends, only serves to weaken the explanatory power of molecular mimicry as a "one size fits all" mechanism in Vaccine Act cases. Opp. at 17 (citing He Rep. at 6).

Besides offering this generalized molecular mimicry argument, Respondent maintains, Petitioner identified only two other pieces of evidence to connect CIDP to the Td vaccine. Opp. at 18. First, Petitioner cited Pritchard, a study that found evidence of CIDP symptoms reoccurring in patients who had received the tetanus vaccine. *Id.* at 19. But Pritchard offers unreliable evidence of causation, as its authors admit. Opp. at 19. The same is true of Pollard and Selby. That case study was reviewed by the IOM but deemed to constitute inadequate support for causation because it did not rule out other possible causes of the patient's neuropathy and did not provide evidence beyond a temporal relationship. *Id.* at 19-20; 2012 IOM Rep. at 559-60. By contrast, a more recent systematic review by Dudley concluded that vaccines that are recommended to the general U.S. population (including those containing tetanus) "have not been shown to cause inflammatory disseminated polyneuropathy." Dudley at e84.

Turning to the second *Althen* prong, Respondent observes that Petitioner's evidence (such as the statements by contemporaneous treaters) mainly emphasizes the temporal relationship between Petitioner's CIDP onset and the vaccine, but without any real effort to rule out alternative explanations for her illness. Opp. at 21-22 (citing *Althen*, 418 F.3d at 1278). Treater views acknowledging the temporal relationship were not the same as opinions as to causality. *Id.* at 22. And given Petitioner's failure to establish a causal relationship under *Althen* prong one, no finding of a medically-acceptable temporal relationship under *Althen* prong three is possible. *Id.* at 23.

V. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[11] There is no Table claim for CIDP caused by a tetanus-containing vaccine. In fact, even in the context of a Table claim for GBS caused by the flu vaccine, a diagnosis of CIDP defeats a Table claim entirely. 42 C.F.R. § 100.3(c)(15)(vi).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface*, 165 F.3d at 1352–53); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

[11] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly

trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are

contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any

norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master

considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Determination to Resolve Case without a Hearing*

I have opted to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

ANALYSIS

I. GBS vs. CIDP

The record clearly establishes that although Petitioner was initially diagnosed with GBS, that diagnosis was later – and properly – revised to CIDP when she experienced a relapse of neurologic symptoms after more than two years (during which her condition was mostly quiescent). Ex. 33 at 14. There is therefore no dispute as to Petitioner's injury. But it would nevertheless be worthwhile to review relevant distinctions between CIDP and GBS.

As explained by Dr. Khella, it is not uncommon for CIDP to present initially like GBS, given the overlap between both conditions. Second Khella Rep. at 2. Because of this overlap, Program petitioners often treat CIDP as merely "long GBS." *See, e.g.*, *Nieves*, 2023 WL 3580148, at *35. And this indeed is what Petitioner ventures. Thus, Petitioner refers to CIDP and GBS as almost-interchangeable "demyelinating neuropathies." Reply at 1. Moreover, Petitioner's briefing discusses GBS at length, devoting only a short section of her Reply to a discussion of CIDP. *See* Reply at 5. And while Petitioner and Dr. Khella have provided extensive medical literature related

to GBS, they have offered very few articles specific to CIDP (specifically Pritchard and Pollard & Selby).

The temptation to avoid distinguishing the two diseases likely stems from the fact that GBS has been credibly linked to certain vaccinations (namely the influenza vaccine), while the evidence supporting a causal link between CIDP and vaccines is less robust. *See Nieves*, 2023 WL 3850148, at *35 ("[E]vidence that strongly supports a GBS-flu vaccine causal relationship rings weaker when applied to CIDP"). But it remains the case that CIDP and GBS are distinguishable, immune-mediated polyneuropathies, even if they share many features. *See, e.g., Houston v. Sec'y of Health & Hum. Servs.*, No. 18-420V, 2021 WL 4259012, at *17 (Fed. Cl. Spec. Mstr. Aug. 19, 2021) (noting CIDP vs. GBS distinctions).

CIDP is defined as "a slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves." *CIDP*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=99346&searchterm=chronic+inflammatory+demyelinating+polyneuropathy (last visited Jan. 17, 2024). CIDP often requires chronic maintenance treatment with IVIG or corticosteroids. van den Berg at 477. GBS, by contrast, is an inflammatory polyneuropathy characterized by an acute onset, rapid progression, symmetric muscle weakness and hyporeflexia or areflexia. Im at 64. GBS is monophasic and unresponsive to steroid treatment (unlike CIDP). *Nieves*, 2023 WL 3580148, at *35. In addition, GBS and CIDP are not understood to have the same self-targets for cross-reactive attack, with CIDP thought to involve damage more to the "nodes of Ranvier" running along a nerve than the myelin sheath generally. *Mason v. Sec'y of Health & Hum. Servs.*, No. 17-1383V, 2022 WL 600415, at *26 (Fed. Cl. Spec. Mstr. Feb. 4, 2022). They thus differ in meaningful ways.

Because of the foregoing, it is improper when deciding a Vaccine Act claim to treat CIDP and GBS as interchangeable.[12] *See Nieves*, 2023 WL 3580148 at *36 ("[T]he overlap between GBS and CIDP cannot be employed as a shortcut to entitlement…"); *see also Howard*, 2022 WL 4869354 at *22 ("[F]or purposes of Program determinations, it is improper to think of GBS and CIDP as 'two sides of the same coin,' despite their overlap…Petitioners cannot just 'borrow' what is known about GBS and vaccination generally as a template for proving causation in the context of a CIDP injury"). I will therefore not blindly apply the evidence supporting a causal link between GBS and other vaccines to this case. While *some* aspects of what is understood about GBS and its

[12] By contrast, other kinds of Program claims involving conditions with multiple titles, all describing the same thing. Brachial neuritis, for example, is also referred to as Parsonage-Turner syndrome, or neuralgic amyotrophy – and therefore it makes no difference what term is used to characterize the diagnosis. *See Marshall v. Sec'y of Health & Hum. Servs.*, No. 21-1445V, 2024 WL 2059813, at *1 n.3 (Fed. Cl. Spec. Mstr. Apr. 12, 2024).

relationship to vaccines may well be relevant to my analysis,[13] Petitioner's success ultimately turns on whether she has preponderantly linked *CIDP* to the Td vaccine.

II. Program Treatment of CIDP as Vaccine-Caused

There is a large body of reasoned decisions affirming the existence of a causal link between the flu vaccine and GBS. Indeed, this causal evidence is the basis for a Table claim. 42 C.F.R. § 100.3.14 This means the Government has agreed that sufficiently-probative and reliable science on the topic exists to justify (in effect) conceding causation, at least for Program purposes. *Haskins v. Secretary of Health & Hum. Servs.*, No. 18-1776, 2020 WL 1870279 (Fed. Cl. Spec. Mstr. Mar. 13, 2020). And the theoretical components relied upon for this association – cross-reaction of antibodies generated in response to a vaccine, due to molecular mimicry – are consistent with what is offered herein.

Because of the similarities between GBS and CIDP discussed above, many Program decisions have assumed that the medical and scientific evidence supporting a GBS-flu vaccine link applies with the same force to CIDP. *See, e.g., Jastisan v. Sec'y of Health & Hum. Servs.*, No. 13-937V, 2016 WL 4761950 (Fed. Cl. Spec. Mstr. Aug. 10, 2016). Special masters thus tend to lump GBS and CIDP together when the flu vaccine is at issue. *See, e.g., Tomsky v. Sec'y of Health & Hum. Servs.*, No. 17-1132V, 2020 WL 5587365, at *5 (Fed. Cl. Spec. Mstr. Aug. 24, 2020) ("[F]or purposes of this decision I merely assume but do not decide that petitioner has established a medical theory causally linking the flu vaccine to CIDP"); *Strong*, 2018 WL 1125666, at *20. I myself have done the same, motivated by a desire to adhere to past Program resolutions of such claims for the sake of judicial consistency. *See Strong v. Sec'y of Health & Hum. Servs.*, No. 15-1108V, 2018 WL 1125666, at *20 (Fed. Cl. Spec. Mstr. Jan. 12, 2018) (finding that the flu vaccine could cause CIDP).

But there are very few *reasoned* decisions linking the flu vaccine to CIDP. And while the aforementioned causation "assumption" may be defensible when the flu vaccine is at issue, it loses its luster when it is extended to different vaccines (which themselves have a weaker association with GBS).

For this reason, I have not extended such thinking to cases involving *tetanus-containing vaccines*. *See Howard*, 2022 WL 4869354 (Tdap vaccine not shown to be causal of CIDP); *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 18-1012V, 2022 WL 1013264 (Fed. Cl. Spec. Mstr. Mar. 11, 2022) (same); *Houston*, 2021 WL 4259012 (same). And many Program decisions have *denied* entitlement in cases where the petitioner alleged a causal link between the Tdap vaccine

[13] As noted below, I have been more willing to elide the CIDP-GBS distinction in cases involving the *flu vaccine* (which the Program has consistently treated as causal of a number of related demyelinating conditions). But this case involves a different vaccine entirely.

and GBS more generally. *See Winkler v. Sec'y of Health & Hum. Servs.*, No. 18-203V, 2021 WL 6276203 (Fed. Cl. Spec. Mstr. Dec. 10, 2021), *mot. for review den'd*, No. 18-203V, 2022 WL 1528779 (Fed. Cl. May 13, 2022), *aff'd*, 88 F.4th 958 (Fed. Cir. 2023); *Montgomery v. Sec'y of Health & Hum. Servs.*, No. 15-1037V, 2019 WL 2511352 (Fed. Cl. Spec. Mstr. May 21, 2019); *Tompkins v. Sec'y of Health & Hum. Servs.*, No. 10-261V, 2013 WL 3498652 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for review den'd*, 117 Fed. Cl. 713 (2014); *see also Isaac v. Sec'y of Health & Hum. Servs.*, 108 Fed Cl. 743 (2013) (affirming special master denial of claim alleging tetanus vaccine was causal of GBS), *mot. for review den'd*, 540 Fed. App'x 999 (Fed. Cir. 2013).

There are admittedly some decisions going the other way. *See, e.g.*, *Mohamad v. Sec'y of Health & Hum. Servs.*, No. 16-1075V, 2022 WL 711604, at *18 n.27 (Fed. Cl. Spec. Mstr. Jan. 27, 2022) (ruling in the petitioner's favor in a Tdap-GBS case, but almost wholly based on determination that the Government had conceded the first *Althen* prong, plus evidence of prior post-vaccination demyelination, suggesting proof of "rechallenge"), *mot. for review den'd*, No. 16-1075, 2024 WL 4943421 (Fed. Cl. Nov. 12, 2024), *appeal docketed*, No. 25-1370 (Fed. Cir. Jan. 16, 2025). But I have noted they are not persuasive in their reasoning. *K.A.*, 2022 WL 20213037, at *24-25. As a result, while it certainly cannot be said that GBS claims relying on tetanus-containing vaccines utterly lack reasonable basis, there is a meaningful decline in the amount of reliable scientific evidence associating the Tdap vaccine and GBS or CIDP that makes it difficult to find causation is established for this vaccine. *Howard*, 2022 WL 4869354 at *22.

III. Petitioner Has Not Carried Her Burden of Proof[14]

A. *Althen* Prong One

A foundational issue with Petitioner's *Althen* prong one showing is her overreliance on evidence primarily relating to GBS, and her assumption that it applies equally to CIDP.[15] As I have explained above, however, more is needed to support causation when CIDP is the injury – and this is especially the case where, as here, a vaccine *other* than the flu vaccine is at issue.

Petitioner made some effort to meet this challenge, both in her arguments and also via the contents of Dr. Khella's second report (although most of its references still involve GBS). *See generally* Second Khella Rep. But she ultimately has not carried her burden on this *Althen* prong.

[14] Because claimants must satisfy all three *Althen* prongs, I do not include a discussion of the third prong. *Dobrydnev v. Sec'y of Health & Hum. Servs.,* 566 Fed. Appx. 976, 980 (Fed. Cir. 2014).

[15] Some of this likely flows from the fact that Petitioner's case was initiated (and the first expert report was filed) *before* her diagnosis had been revised to CIDP.

First, Petitioner's homology showing (a foundational requirement for invocation of molecular mimicry as an autoimmune mechanism) is simultaneously too limited and too broad. The best item of evidence she offers for a possible homologic sequence between the vaccine and myelin, Bavaro, involves the diphtheria *toxin* (not the vaccine's *toxoid* component)[16] – and it is less likely the toxoid would have the same immunogenically-aberrant capacity. *Tipps v. Sec'y of Health & Hum. Servs.*, No. 16-867V, 2023 WL 183398, at *21 (Fed. Cl. Spec. Mstr. Jan. 13, 2023) (explaining that the toxoid component of the Tdap vaccine is less likely to cause harm than the wild infectious toxin). At the same time, the vast majority of evidence she offers, whether a case report or study, relates to the *tetanus* component (not the *diphtheria* component). *See*, *e.g.*, Pollard & Selby at 113 (patient suffered three episodes of neuropathy, each of which followed an injection of tetanus toxoid); Newton at 1054 (patient developed GBS after injection of pure tetanus toxoid); Ammar at 1-2 (discussing the tetanus toxoid in connection with patient's GBS); Bakshi at 202 ("[W]e suspect that the tetanus portion of the vaccination produced GBS"). Some showing of homology should have been made with respect to *tetanus* as well, since it is so frequently the focus of such evidence.

Furthermore, and as Respondent notes, Bavaro establishes *so much* possible homology between the diphtheria toxin and self-structures/sequences that the incidence of autoimmune disease should be substantially higher than it is in the population, undermining the significance of its findings. Bavaro's authors themselves acknowledged that the level of peptide sharing between viral/bacterial proteomes is "unexpectedly high." Bavaro at 360 (identifying 4,966 shared sequences between diphtheria pentapeptides and human proteins). Dr. He's report, relying on Kanduc, emphasizes how common homology actually is – without consistently being pathogenic. All proteins are built from the same 20 amino acids, so it is inevitable in the human biome that sequences of amino acids will repeat. *Tullio v. Sec'y of Health & Human Servs.*, No. 15-51V, 2019 WL 7580149, at *15 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), *mot. for review den'd*, 149 Fed. Cl. 448 (2020).

All such evidence relating to the possibility of cross-reactivity between the Td vaccine's components and nerve myelin due to homology also runs into a different obstacle: *demonstration of homology alone is not enough to establish a preponderant causation theory*. *Caredio v. Sec'y of Health & Human Servs.*, No. 17-79V, 2021 WL 4100294, at *31 (Fed. Cl. Spec. Mstr. July 30, 2021), *mot. for review den'd,* No. 17-79V, 2021 WL 6058835 (Fed. Cl. 2021). A finding of homology thus offers minimal utility in establishing molecular mimicry as a likely explanation for vaccine causation when it is not linked to other corroborative evidence. *See* 2012 IOM Rep. at 70 ("Linear amino acid sequence homology or even similar conformational structure between an exogenous agent and a self-antigen alone are not sufficient to prove that molecular mimicry is the

[16] The Td vaccine contains the tetanus toxoid and diphtheria toxoid. *Ingredients in Td Vaccines*, Children's Hospital of Philadelphia, https://www.chop.edu/vaccine-education-center/vaccine-safety/vaccine-ingredients/ingredients-by-vaccine/td-vaccines-ingredients (last visited Feb. 4, 2025).

pathogenic mechanism for a disease"). And the fact that molecular mimicry is a reliable mechanism to explain *some* autoimmune diseases does not mean it has utility in *all* Program cases.

This leads to the second deficiency in Petitioner's theory: the overall lack of reliable evidence specific to the Td vaccine, or other vaccines containing tetanus like Tdap.[17] What is known about GBS (an acute and monophasic condition) cannot be just thoughtlessly transplanted into this context. And Petitioner's evidentiary showing provides no explanation for how a transient vaccination event could "set up" a chronic process that would relapse and remit over a period of a two-plus years.[18] Petitioner has not even offered a proposed target situs for the autoimmune attack presumed to have occurred, and instead seems to assume that the Td vaccine could act like the flu vaccine in causing a GBS-like presentation, but then also impact the immune system somehow to result in chronic symptoms later.

Third, any corroborative additional evidence Petitioner has marshalled to link CIDP to the Td vaccine is unreliable or unpersuasive. She mainly references case reports – a kind of evidence not generally given significant weight when evaluating causation. *See Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011) ("Case reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value compared particularly to formal epidemiological studies"). And the majority of these reports relate to GBS, not CIDP. *See* Kongbunkiat, Bakshi, Newton.

The evidence that has been offered specific to CIDP is itself largely unreliable. Pritchard, for example, purports to observe a significant risk of recurring CIDP symptoms following tetanus vaccination. Pritchard at 348-49. But Pritchard's methodology reflects selection bias, as its conclusions were derived from questionnaire responses rather than objectively-confirmed medical evidence. *Johnson v. Sec'y of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760, at *24 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) (discussing problems with self-selection studies); *Evanson v. Sec'y of Health & Human Servs.*, No. 90-775V, 1991 WL 179085, at *4 (Fed. Cl. Spec. Mstr. Aug. 28, 1991) (discussing "major methodological problems" of studies based on self-reporting); *see also* Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 583–97 (3d ed. 2011) (discussing problems of selection bias and informational bias in self-selected studies, potential for confounding factors to erroneously imply existence of a causal relationship, and inferiority of self-selection studies to observational studies). In fact, *Pritchard's own authors* even acknowledged this to be

[17] Although Petitioner has offered some evidence linking a wild tetanus toxin infection to neurologic conditions, corroboration of a *vaccine association* was more important (especially since, as Dr. He established, a wild infection will inherently provide greater immune system stimulation, and therefore more opportunity for harm).

[18] Importantly, Petitioner has not alleged that the Td vaccine caused Petitioner *only* to experience GBS (and hence that Petitioner's subsequent CIDP diagnosis is somehow unrelated). Nor does she contend that vaccine-induced GBS could through other means evolve into CIDP. Rather, she accepts the CIDP diagnosis (despite some efforts to blur the lines between it and GBS). Br. at 34. And even if she had so alleged, I would find on this record that Petitioner's injury *is CIDP* – and thus that the initial diagnosis of GBS was based on incomplete evidence, and ultimately incorrect.

the case. Pritchard at 349. Furthermore, Pritchard involved post-vaccination relapses only – not first-time occurrences of CIDP – and the study does not provide a scientific explanation for the supposed causal link.

Pollard & Selby deserves even less weight. In this quite-old case study, a patient's acute idiopathic polyneuropathy relapsed on three occasions, each purportedly following a tetanus vaccination. Pollard & Selby at 113. But its authors did not consider alternative explanations for these spontaneous relapses, nor did they provide evidence beyond a temporal association. 2012 IOM Report at 559-60. The authors also failed to explain *how*, or by *what* mechanism, a tetanus toxoid antigen could stimulate CIDP, even if some association had been demonstrated in this single patient. *Howard*, 2022 WL 4869354, at *11.[19] And Pollard & Selby's findings remain uncorroborated, over 45 years later, by subsequent (and more reliable) studies that might confirm what it suggests is possible. It cannot stand as persuasive evidence for causation. *Tompkins*, 2013 WL 3498652, at *26 (observing that an absence of evidence in the years after publication of a case report or series corroborating its suggestions about a vaccine-injury association undermines the initial report's causal significance, and suggests its findings reflect only chance).[20]

There is also the question of various IOM reports involving tetanus-containing vaccines and their alleged link with GBS. Petitioner correctly notes that other special masters have given weight to the IOM's varying views on the topic (and in some cases have gone so far as deeming the matter conceded). See *Mohamad*, 2022 WL 711604, at *18; *Harris*, 2023 WL 2583393, at *27. Of course, the determinations of other special masters do not bind me – and I have previously noted that *Mohamad's* reasoning is not wholly persuasive in treating the issue of causation as conceded in any form by the Government. *K.A.*, 2022 WL 20213037, at *25.

But there is a more fundamental problem with the contention that different IOM report iterations (which largely pertain to GBS) might allow for an association between peripheral neuropathies and tetanus-containing vaccines, with earlier ones entitled to comparable weight to later ones, even if they are not congruent. For the logic employed in *Harris* and *Mohamad* was

[19] As explained in more detail in *Howard*, it was in fact unclear whether the subject patient in Pollard & Selby could properly be diagnosed with CIDP (although the chronic and relapsing nature of his symptoms echoed it). *Howard*, 2022 WL 4869354, at *7, 11. In addition, its authors speculated the tetanus toxoid encouraged the injury through "a non-specific, cellular, T cell-driven myelin attack," as opposed to due to antibodies generated in response to the vaccine (and therefore via a mechanism different in nature from the kind of autoimmune attack understood to occur in the flu vaccine-GBS context). *Id.* at *11.

[20] This is, in fact, the prime value of a case report (as many experts have stated in Program cases): its utility as a "signal" inviting future, more rigorous scientific study to test the hypotheses it suggests. When a case report observing a possible association is *never* followed up by later scientific research, even after many years of opportunity to do so, it is fair to question its unconfirmed, speculative assumptions. *See Nieves*, 2023 WL 3580148, at *45 ("[I]f they are not bulwarked with other reliable proof, whatever the form or nature, case reports cannot by themselves constitute the basis for a causation finding, since they do little more than delineate an instance in which an injury temporally followed vaccination").

called into question years before their respective publication, in *Tompkins*. There, former Chief Special Master Vowell was tasked with determining whether a number of disparate vaccines, including tetanus-containing vaccines, could cause GBS. That decision includes a lengthy and specific discussion of each relevant vaccine – including the tetanus vaccine. *Tompkins*, 2013 WL 3498652, at *23-30. With respect to tetanus, Special Master Vowell noted that a 1994 version of the IOM report seemed to allow for a tetanus-GBS association, but was supplanted by a 2011 version "concluding that epidemiologic evidence was insufficient to demonstrate a causal association between tetanus toxoid and GBS." *Id.* at *26.[21] Thus, the progression of science's understanding of vaccine-injury association must be given weight when considering different iterations of government reports; an earlier report is not per se entitled to the same weight, simply because at one time (and based on less evidence) it reached a slightly different conclusion.

Otherwise, perhaps the *most* this IOM evidence stands for is recognition of a *potentially increased risk* of a demyelinating polyneuropathy (assuming for a moment the GBS-CIDP congruence Petitioner might prefer I observe) *relapse* after receipt of a tetanus-containing vaccine – not that the vaccine would likely be capable of triggering CIDP *initially*. *K.A.*, 2022 WL 20213037, at *24 ("The special master in *Mohamad* gave special emphasis to a 2019 publication that (consistent with the package insert[22] offered in this case) offered as a 'precaution' that Tdap was to be carefully considered for individuals who previously had experienced GBS within six weeks of a tetanus toxoid-containing vaccine's prior receipt"). Evidence a vaccine could promote a neuropathic flare does not also mean it can be causal of the original injury. *See, e.g.*, *Porch v. Sec'y of Health & Hum. Servs.*, No. 17-802V, 2023 WL 21875, at *13 n.39 (Fed. Cl. Jan. 3, 2023) ("[V]accination is associated with transient systemic reactions—and for MS patients this can encourage a response akin to a symptoms flare"). And Petitioner does not otherwise allege her CIDP was a vaccine-caused aggravation of an underlying condition.

Ultimately, CIDP is different enough from GBS to require reliable evidence *specific* to it. Such evidence should elucidate what are suspected to be the autoimmune drivers of the condition, how this form of neuropathy becomes chronic (and hence not suppressed by the immune system's self-regulating modalities), and what environmental triggers might explain its initiation. Comparatively much more is known about GBS, which presents acutely and resolves soon after (even though it can leave persistent and debilitating sequela in its wake). But that same degree of knowledge does not exist for CIDP. To blithely apply "GBS thinking" to CIDP is mistaken, and

[21] Ironically for present purposes, one of the reasons Special Master Vowell gleaned for the change in position between the different reports was the determination by the IOM to *remove* consideration of Pollard & Selby as evidence of a GBS-tetanus association (since Pollard & Selby likely involved CIDP – a distinguishable condition). *Id.* at *27. This only further undermines reliance on governmental reports as evidence of a GBS-CIDP link, when those reports do not involve CIDP in the first place.

[22] *Adacel, Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine*, Package Insert, Sanofi Pasteur, filed as Ex. A.13 (ECF No. 23-3).

does not meet the preponderant evidentiary test applicable to all *Althen* prongs. I therefore find that the first *Althen* prong is unsatisfied.

B. Althen Prong Two

Petitioner was equally unable to show that the Td vaccine "did-cause" her CIDP. For support, she mainly relies on statements from her treating providers. *See* Ex. 7 at 17 ("54-year-old female with a history of inflammatory neuropathy after tetanus booster vaccinations"); Ex. 3 at 6. But aside from acknowledging a temporal association, these treaters never expressed an opinion on causation, or provided a reasoned explanation of how the two were associated. The notes from these treatment incidents simply state that Petitioner was diagnosed with an inflammatory neuropathy "after" receiving the tetanus vaccine. Ex. 7 at 4, 17. While it may have been reasonable and appropriate for treaters to take note of the fact of a prior vaccination, such notations do not constitute evidence that treaters deemed the vaccine causal.

Furthermore, Program law clearly does not obligate special masters to accept as sacrosanct the statements of contemporaneous treaters. *Snyder v. Sec'y of Health & Hum. Servs.*, No. 01-162V, 2009 WL 2569773 at n.67 (Fed. Cl. Spec. Mstr. Aug. 11, 2009) ("However, there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). And here, those statements from their context seem mainly to find significant the kind of temporal association that is not deemed sufficient to prove causation. *Althen*, 418 F.3d at 1278 ("[N]either a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation").

Otherwise, the record does not establish a factual basis for deeming the vaccine to have been significant in producing Petitioner's injury. No test result or diagnostic evaluation suggests vaccination prompted what followed. Nothing about the nature of Petitioner's neuropathic symptoms seem aligned with vaccination as causal. And Petitioner did not even experience any kind of suspect reaction post-vaccination that would imply an aberrant immune process was underway. She simply began to experience neuropathic symptoms two weeks post-vaccination.

CONCLUSION

Preponderant evidence does not support Petitioner's causation theory. She is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[23]

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[23] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.